

*Sub B2*  
6. (Amended) A vaccine suitable for oral or intranasal administration comprising an effective amount of a hydrophobic complex [according to any one of claims 1, 2, 3, 4 and 5] consisting essentially of proteosomes and at least one antigenic lipopolysaccharide and a carrier.

*Sub B3*  
7. (Amended) A method for providing enhanced immunogenicity comprising administering the immunogenic composition of any one of claims 1-4 or the vaccine of claim [5] 6 to a subject [parenterally,] orally[,] or intranasally[ or topically].

*Sub B1*  
8. (Amended) A method of achieving immunity by administering the immunogenic composition of any one of claims 1-4 or the vaccine of claim [5] 6 to a subject [parenterally,] orally[,] or intranasally [or topically] to impart immunity. *13, 14, 15*

*Sub B4*  
16. (Amended) A method of achieving immunity according to claim 8 by administering the immunogenic composition of any one of claims 1-4 or the vaccine to mucosal surfaces selected from the group of respiratory, gastrointestinal, vaginal, nasal, rectal and oral mucosa.

#### REMARKS

Reconsideration is respectfully requested in light of the forgoing amendments and the following remarks.

Claims 1-4 and 6-16 are before the Examiner. Claim 1 has been amended to characterize the lipopolysaccharide as a component of an immunogenic composition suitable for oral or intranasal administration. Support for the added language is found on page 11 starting at line 13 and continuing to page 12, line 5 of the specification. Claim 5 has been canceled.

Formal drawings will be submitted when the application is allowed.

Regarding the margins, a "duplicate" specification will be submitted to make the necessary corrections when the application is indicated to be allowable.

### **Rejections under 35 USC 112, Second Paragraph**

Claims 7-16 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

The claims have been amended in accordance with the Examiner's suggestions. Withdrawal of the rejection is respectfully requested.

### **Rejections under 35 USC 102(b)**

Claims 1 and 4-12 stand rejected under 35 USC 102(b) as being anticipated by Zollinger *et al.* (4,707,543). Applicant respectfully traverses.

Claim 1 has been amended to limit it to a composition that is suitable for oral or intranasal administration. Such a composition is not taught by Zollinger *et al.* Since the reference does not teach each and every element required by the claim, it is not anticipatory. With regard to the inherency of the characteristic(s), there must be reasonable certainty of its presence. The reference is silent as to both oral and intranasal administration. There is no mention of an equivalent mode of administration. Further, there is no mention of protective antibodies on mucosal surfaces or administration to these surfaces. Only conventional injection is specifically mentioned.

Accordingly, Applicants respectfully request that the rejection of Claims 1 and 4-12 under 35 USC 102(b) be withdrawn.

### **Rejections under 35 USC 103**

Claims 2, 3, 14, 15 and 16 stand rejected under 35 USC 103 as being unpatentable over Zollinger *et al.* (4,707,543) in view of Cohen *et al.* (J. Infect. Dis., 1988, 157(5): 1068-1071) and Black *et al.* (J. Infect. Dis., 1987, 155(6): 1260-1265) and in further view of Ruegg *et al.* (J. Immunol. Methods, 1990, 135: 101-109). Applicant respectfully traverses.

The deficiencies of Zollinger *et al.* are noted above. These deficiencies are not remedied by the teachings of the secondary references.

Accordingly, based on the foregoing, Applicants respectfully request that the rejection of Claims 2, 3, 14, 15 and 16 under 35 USC 103 be withdrawn.

### Rejections for Double Patenting

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,985,284.

Applicant respectfully requests that a response to this ground of rejection be held in abeyance until the application is found to be otherwise in condition for allowance. Applicant is under a preexisting obligation to assign his rights to the claimed invention to the U.S. Government, his employer, at the time of invention. The filing of a terminal disclaimer is appropriate for resolution of this invention. Note U.S. application No. 07/958,426 in this regard.

### CONCLUSION

Each matter of substance raised by the Examiner has been addressed. No new matter has been added with the amendment. Applicant believes that the case is in condition for allowance. The Examiner is invited to contact Applicant's agent at the number listed below if it would be helpful in any way to resolve any remaining issues.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 406462000102. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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By:

  
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